

EXHIBIT 2

In The Matter Of:
In Re: Ethicon, Inc.

Mark Norvell, M.D.
05/31/2013

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY
LITIGATION

MDL 2327

LILLIE HARRIET CREWS and WAIN
CREWS,

Civil Action File
No. 2:12-cv-01549

Plaintiffs,

vs.

ETHICON, INC., ETHICON, LLC, and
JOHNSON & JOHNSON,

Defendants,

THE VIDEOTAPED DEPOSITION OF MARK K. NORVELL, M.D.

May 31, 2013

10:53 a.m.

Holiday Inn, 138 Glynco Parkway

Brunswick, Georgia

Maureen S. Kreimer, RPR, CCR-B-1379, LCR-061

Terry Wetz, Legal Video Specialist

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1 over a number of years, has it not?

2 **A. It has.**

3 Q. And prior to today, you have met with me,
4 have you not?

5 **A. Yes, I have.**

6 Q. On two occasions?

7 **A. True. Well, three counting this morning.**

8 Q. And they -- and you have -- I can't
9 remember the third one, Doctor.

10 **A. Well, I'm sorry. Two with you. One with**
11 **your paralegal and --**

12 Q. Partner?

13 **A. Was the first time, right.**

14 MS. DEMING: I'm sorry. What was the
15 last thing?

16 A. Ann Parker. I met with her on one
17 occasion and then Mr. Blassingale [sic] on this
18 morning and a previous occasion.

19 MS. DEMING: And you understood
20 Ms. Parker to be with his firm?

21 THE WITNESS: Exactly, mm-hmm.

22 MS. DEMING: Okay.

23 MR. BLASINGAME: Ms. Parker is a
24 paralegal at our law firm.

25 BY MR. BLASINGAME:

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1 Q. And then we met -- you and I met this
2 morning, did we not?

3 A. That's correct.

4 Q. And we discussed your care and treatment
5 of Mrs. Crews?

6 A. That's correct.

7 Q. And we discussed some Ethicon documents,
8 did we not?

9 A. We did.

10 Q. Those are documents that some parts of
11 which I shared with you, is that fair?

12 A. That's correct.

13 Q. We discussed what's known as
14 "instructions" for use for the product that she
15 received, did we not?

16 A. We did.

17 Q. Okay. Have you met with anyone else
18 other than your lawyer about this matter?

19 A. About this case, or --

20 Q. Yes, sir.

21 A. No, I haven't.

22 Q. At the time you were in medical school,
23 had trans -- had the use of transvaginal mesh come
24 along?

25 A. No, it had not; at least to my knowledge,

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1 making notes.

2 MR. BLASINGAME: She's making notes with
3 a shake of the head, so...

4 BY MR. BLASINGAME:

5 Q. Doctor, would a better question be do you
6 expect the manufacturer to present a complete
7 picture of the risk and potential complications of a
8 medical device like Prolift to the extent that the
9 manufacturer has such knowledge?

10 MS. DEMING: Object to the form.

11 A. I would expect that, yes.

12 BY MR. BLASINGAME:

13 Q. You're familiar with instructions for
14 use, the IFU?

15 A. **Mm-hmm (affirmative).**

16 Q. In fact, we have gone over that for this
17 product, have we not, sir?

18 A. **We have.**

19 Q. And what is your understanding, sir, of
20 what an IFU is?

21 A. **Well, I guess it's documentation from the**
22 **manufacturer that's supposed to inform the physician**
23 **of the use of its product.**

24 Q. And tell me, please, sir, how you have
25 related to IFUs, if any, during your practice; and

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1 THE VIDEOGRAPHER: We are back on the
2 record. The time is 12:00. You may continue.
3 BY MR. BLASINGAME:

4 Q. Doctor, am I correct that the
5 implantation of the Ethicon Prolift device into
6 Lillie Crews was on -- was in February of 2009?

7 A. I believe that's correct, yes.

8 Q. I'd like to call your attention to a
9 document that has been produced by Ethicon dated
10 February 23rd, 2007, which would be two years --

11 A. Okay.

12 Q. -- before Lillie was implanted. And if
13 you don't --

14 MR. BLASINGAME: Terry, if you'll pull
15 up --

16 MS. DEMING: Which document? Is it one
17 of the ones you gave me yesterday? Which one is it?

18 MR. BLASINGAME: Yes.

19 I'm going to give you a copy of it.

20 Terry, if you'll pull up Document 48,
21 and...

22 MS. DEMING: Are you going to mark it
23 as --

24 (Plaintiff's Exhibit #1 marked)

25 BY MR. BLASINGAME:

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1 Q. Doctor, I'm going to show you this
2 document, which is on the screen up there.

3 MR. BLASINGAME: And I'm going to ask the
4 videographer to turn to Page 207155 of that
5 document, which is about four pages in.

6 MS. DEMING: Okay. And unless you -- I
7 mean, I don't know how you're going about this, but
8 there is no foundation to this document. So showing
9 it at this time to the doctor without establishing a
10 foundation, I object to.

11 MR. BLASINGAME: It came from your files.

12 MS. DEMING: What number did you say,
13 what page number?

14 THE WITNESS: 55.

15 MS. DEMING: Okay. Got it.

16 MR. BLASINGAME: 55.

17 BY MR. BLASINGAME:

18 Q. Doctor, this document says on its face
19 that it is an Ethicon Expert Meeting: Meshes for
20 Pelvic Floor Repair.

21 And if I look at Page 1 for a second, the
22 document shows the external participants as
23 Professor M Cosson; Professor BK Klosterhalfen;
24 Professor J Deprest; Professor B -- I can't
25 pronounce that.

1 MS. DEMING: Jacuetin.

2 BY MR. BLASINGAME:

3 Q. Jacuetin. And then Dr. Arit, Dr. D
4 Miller and Dr. K Lobodasch.

5 MS. DEMING: Gary, before you go on, can
6 I just have a standing objection so I don't have to
7 object to the foundation and form throughout these
8 documents?

9 MR. BLASINGAME: Absolutely.

10 BY MR. BLASINGAME:

11 Q. And this document states that it is an
12 Introduction and Update of Project LIGHTning, which
13 I think if you read the entire document you would
14 see that that is another product they are intending
15 to put on the market.

16 A. For the vagina?

17 MS. DEMING: Object to the form.

18 BY MR. BLASINGAME:

19 Q. Yes.

20 A. Yes.

21 Q. And if you will look on Page 7155 the
22 document says: "The following summary of unmet
23 needs generated June the 2nd of 2006 was again
24 confirmed without any adding."

25 And one of the unmet clinical needs says

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1 "no shrinkage/no long-term contraction."

2 If you look at the priority over there,
3 that's 10 points.

4 **A. Mm-hmm (affirmative).**

5 Q. The next one is "fibrosis reduction."

6 And the next one is: Severe contraction, with an
7 arrow to dyspareunia, an arrow to sexual function.

8 And then the next block, an eight is "no
9 vaginal distortion, normal vaginal wall, maintain
10 sexual function, normal sexual function.

11 Doctor, if this document, which mentions
12 a previous document of June of '06, if this document
13 is -- shows the knowledge of Ethicon as of
14 February 23rd, 2007, if you had had this knowledge
15 before you implanted Lillie Crews with a Prolift
16 product, would you have been concerned about whether
17 or not to put this product in Lillie Crews?

18 MS. DEMING: Object to the form. You've
19 already noted that it's obviously not a complete
20 document because it references other documents, and
21 it's clearly the notes of somebody. So it's
22 inappropriate to be questioning this -- or making
23 assumptions about this document when you haven't
24 even established foundation.

25 MR. BLASINGAME: I think that all

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1 objections are reserved except as to the form of the
2 question.

3 MS. DEMING: And I am objecting to the
4 form on an additional ground.

5 MR. BLASINGAME: I think that was a
6 speaking objection.

7 BY MR. BLASINGAME:

8 Q. But go ahead. Doctor, can you answer the
9 question?

10 A. Had I had access to this information, I
11 would have been less likely to consider putting a
12 mesh in.

13 Q. Well, let's go back, Doctor, to a
14 December the 12th project, "Charter," they call it.
15 This will be Number 47 --

16 A. December.

17 Q. -- December the 12th, 2006, which is a
18 previous document. And if I look on Page 15 of that
19 document --

20 MS. DEMING: Can you -- so I can be
21 finding it, are you going through these records in
22 the order that you listed them in your letter
23 yesterday, or --

24 MR. BLASINGAME: No, not necessarily.

25 MS. DEMING: So it's going to take me a

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1 THE VIDEOGRAPHER: Stand by. Just a
2 second, sir. Get this going again.

3 And we are back on the record. The time
4 is 12:12.

5 MR. BLASINGAME: (To videographer) Would
6 you show us the first page of that document for just
7 a moment, please, 26733.

8 BY MR. BLASINGAME:

9 Q. -- and, Doctor, you will see that the
10 first page of that document deals with -- the
11 identification of it is LIGHTning Project Charter,
12 December the 6th, 2012.

13 MS. DEMING: Just to be certain, Gary,
14 any of these documents that are from -- purport to
15 be from Ethicon I have a standing objection to with
16 respect to foundation. I don't need to be
17 interrupting you.

18 MR. BLASINGAME: You do, and you do not.

19 MS. DEMING: Okay. Thank you very much.

20 BY MR. BLASINGAME:

21 Q. Okay. Doctor, if you will look at
22 Page -- and we will -- at Page 20 of this document.

23 **A. Mm-hmm (affirmative).**

24 Q. And if -- when you've had an opportunity
25 to look at it, I'd like to ask you a couple of

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1 questions about it. But that's the only copy I
2 have.

3 MS. DEMING: The Bates number, though, is
4 00267752.

5 MR. BLASINGAME: That's right.

6 MS. DEMING: You referred to it as Page
7 20.

8 MR. BLASINGAME: Yes.

9 MS. DEMING: Okay.

10 BY MR. BLASINGAME:

11 Q. Now, may I -- I want to ask you a couple
12 of questions --

13 A. Okay.

14 Q. -- about that, Doctor.

15 A. Okay.

16 Q. Doctor, this says -- this is headed Value
17 Proposition. And it says Benefit. He's talking
18 about the LIGHTning document -- "Benefit. May
19 reduce complications and side effects of mesh
20 repair. May reduce incidents of recurrence. Better
21 handling. Improved confidence to use synthetic
22 graft."

23 And then -- that's for the clinician.

24 And for the payor, "may reduce procedures
25 for complications recurrence and associated costs."

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1 Now, if you will keep that in mind, and
2 then look at what may -- what refers to the patient.
3 It says: "Potential better quality of life. May
4 reduce pain (nerve irritation to mesh implant). May
5 reduce risk of dyspareunia. Potentially less
6 exposure, subsequent re-operation. Potentially less
7 recurrence of prolapse."

8 Doctor, if you had had the information
9 on -- that is depicted on this document at the time
10 you implanted Lillie Crews, can you tell us whether
11 or not you would have had pause and recommended to
12 her the implantation of the Prolift?

13 MS. DEMING: Object to the form.

14 A. Let me understand. If I understand this
15 document, they were working on a new mesh outside of
16 the Prolift?

17 BY MR. BLASINGAME:

18 Q. I believe, Doctor, that that's correct.
19 But that will have to be proven later.

20 A. Okay. And are we speaking about Prolift
21 here, or are we talking about --

22 Q. We're talking about Prolift.

23 A. The benefits of LIGHTning over Prolift?

24 Q. Yes, sir.

25 MS. DEMING: Objection to the form.

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1 Object to his characterization of what this is.

2 A. Okay. Well, if I understand what I just
3 clarified there, they recognized these problems with
4 the Prolift, were coming out with a new product to
5 fix those problems. I was not aware of those being
6 major problems in my position as a physician between
7 2006 and 2009.

8 BY MR. BLASINGAME:

9 Q. In that same document on Page 7839 --

10 MS. DEMING: Can -- are you going to mark
11 that as an Exhibit?

12 MR. BLASINGAME: I will.

13 MS. DEMING: Okay. If you'll do that, so
14 we know which documents we are referring to.

15 (Plaintiff's Exhibit #2 marked)

16 MR. BLASINGAME: I think you have passed
17 it. That's it, isn't it? Is that Page 7839?

18 THE VIDEOGRAPHER: Yes, sir. Page 107?

19 MR. BLASINGAME: Page 107.

20 BY MR. BLASINGAME:

21 Q. Doctor, on Page 107 of this document
22 which is Bates number 00267839, it is captioned
23 Unmet Customer Needs. And the unmet customer need
24 is to: "Minimize shrinkage, vaginal stiffness,
25 dyspareunia and permanent pain"; to "lower the rate

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1 of recurrence due to less tissue contraction"; and
2 to "minimize exposure."

3 If as early as 2006 Ethicon was concerned
4 with the unmet need to minimize shrinkage, vaginal
5 stiffness, dyspareunia, and permanent pain, is that
6 knowledge that you would like to have had in
7 determining whether or not to implant or recommend
8 implantation into Mrs. Crews?

9 MS. DEMING: Object to the form.

10 A. Yes, this would have been important
11 information to have had beforehand.

12 MR. BLASINGAME: Okay. We're going to
13 mark this as Exhibit 2. If we could go off the
14 record just a moment.

15 MS. DEMING: You just marked it as
16 Exhibit 2, didn't you?

17 MR. BLASINGAME: Yes.

18 MS. DEMING: Oh, okay.

19 THE VIDEOGRAPHER: We're off the record.
20 The time is 12:19.

21 (Off the record 12:19-12:21 p.m.)

22 MR. BLASINGAME: This will be No. 3.

23 (Plaintiffs' Exhibit #3 marked)

24 THE VIDEOGRAPHER: We're back on the
25 record. The time is 12:21. You may continue.

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1 comment on this page.

2 BY MR. BLASINGAME:

3 Q. All right, sir. Thank you.

4 MR. BLASINGAME: Number 53.

5 MS. DEMING: Number -- and it's what on
6 the list that you gave me, or rather the Bates
7 numbers?

8 MR. BLASINGAME: 02923305.

9 THE WITNESS: Same document, different
10 page or different document?

11 MS. DEMING: No, no. It's different.
12 Say it again, Gary, please. 02923305? That's the
13 first page of the document you're referring to?

14 MR. BLASINGAME: 02923305.

15 MS. DEMING: Okay. And are you going to
16 mark this as Exhibit No 4?

17 MR. BLASINGAME: Yes.

18 (Plaintiff's Exhibit #4 marked)

19 BY MR. BLASINGAME:

20 Q. Doctor, if you will assume that Anne
21 Doherty is a Professor of Urogynecology at King's
22 College Hospital in London.

23 **A. Okay.**

24 Q. That's not true. I'm sorry. If you will
25 assume that Linda Cardozo is a professor of

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1 urogynecology at King's College Hospital in London.

2 **A. Okay.**

3 Q. If you -- and if you will assume, sir,
4 for the purpose of this question that she's a
5 well-known outstanding urogynecologist.

6 **A. Okay.**

7 Q. And if you will assume that she has
8 written this letter to Ann Doherty and others at
9 Ethicon, and that this letter regards -- is in
10 regards to a training session to be held in Lille, I
11 believe that would be France.

12 And assume that she's writing to the
13 group on August the 9th of 2005, that: "I thought I
14 would just let you know that I find the safety
15 profile quite worrying, and hope that this will be
16 discussed in some detail, especially in view of the
17 fact that we have no efficacy data to date." And
18 the subject is Prolift.

19 **A. Right, right.**

20 MS. DEMING: I'm objecting to your
21 characterization of these letters and these
22 assumptions that you've asked him to make about a
23 document that you haven't established even
24 foundation for.

25 BY MR. BLASINGAME:

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1 Q. And assume further, Doctor, that she
2 says: "It is not that there were a lot of
3 complications, it's severity and type of
4 complications and these were just the perioperative
5 notes. I still have major concerns regarding
6 erosion rate and possible problems with dyspareunia,
7 and none of these have been addressed in the data
8 which we have been given to date."

9 If you assume the facts that I have asked
10 you to assume, and assume that this well-known
11 urogynecologist is giving this information to
12 Ethicon, is this information that you would like to
13 have had before you implanted this device in Lillie
14 Crews?

15 MS. DEMING: Object to the form.

16 A. Yes. It's information I would have like
17 to have had.

18 BY MR. BLASINGAME:

19 Q. Is it something that you would -- is it
20 something that might very well have prevented you
21 from using this product in Lillie?

22 MS. DEMING: Object to the form.

23 A. It's quite possible it would have changed
24 my treatment of Lillie Crews.

25 MR. BLASINGAME: Let's go off the record

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1 MS. DEMING: It is in there.

2 MR. BLASINGAME: It is in the records,
3 but we'll make it --

4 MS. DEMING: Thank you.

5 MR. BLASINGAME: -- another copy.

6 MS. DEMING: His record just seemed to be
7 a little unclear.

8 THE WITNESS: Because I don't need it.

9 MR. BLASINGAME: You don't need it.

10 MS. DEMING: Thank you.

11 (Plaintiff's Exhibit #6 marked)

12 THE VIDEOGRAPHER: Which one?

13 MR. BLASINGAME: 28.

14 THE WITNESS: I'm sorry. What was your
15 last question?

16 (The court reporter read back
17 the referred-to portion as follows:

18 Q. And the product was a Prolift product;
19 right?")

20 **A. Yeah. And that's correct.**

21 BY MR. BLASINGAME:

22 Q. And, Doctor, I'm going to show you, IFU
23 or instructions for use, on the Prolift, Total
24 Prolift floor repair, also the anterior and the
25 posterior.

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1 MR. BLASINGAME: Give you a copy of that.

2 MS. DEMING: Yes, please.

3 BY MR. BLASINGAME:

4 Q. And if you would mark that, please,
5 ma'am.

6 COURT REPORTER: No. 7.

7 MR. BLASINGAME: No. 7.

8 (Plaintiffs' Exhibit #7 marked)

9 BY MR. BLASINGAME:

10 Q. You and I looked at this earlier, did we
11 not?

12 **A. This is the one from 2008.**

13 Q. Mm-hmm. And I will ask you to turn to --

14 **A. Okay.**

15 Q. -- I'll ask you to turn to Page 2 of that
16 document.

17 **A. Okay.**

18 Q. And there are a list of contraindications
19 here. Did Lillie Crews fit into any of the
20 contraindications there, Doctor?

21 **A. No, she did not.**

22 Q. And then there is a Adverse Reaction
23 section on Page 3 of that document.

24 **A. Yes.**

25 Q. And, in general, this is what you've

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1 Q. I introduced myself earlier, I'm Kay
2 Deming.

3 A. Okay.

4 Q. I represent Ethicon in this action.

5 A. Okay.

6 Q. And I have got questions, obviously, in
7 response to some of the things that Mr. Blasingame
8 went over with you today. So I'll try to make it as
9 quick as possible.

10 A. Okay.

11 Q. But some things will take longer than
12 others.

13 A. I understand.

14 Q. Have you ever met me before?

15 A. I don't recall if I've ever met you --
16 meeting you.

17 Q. Have you met anybody from my office
18 before?

19 A. I don't believe I have.

20 Q. Now, you met with the Plaintiffs'
21 attorney, Mr. Blasingame, you said twice?

22 A. Twice, mm-hmm.

23 Q. And once with his paralegal?

24 A. That's correct, mm-hmm.

25 Q. When was the meeting with the paralegal?

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1 **A. I don't remember the exact date.**

2 Q. How many months ago? Was it recently,
3 or?

4 **A. Yeah, it was fairly recently. I would**
5 **say four to five weeks ago.**

6 Q. Okay. And what did you go over with her,
7 if anything?

8 **A. She gave me a copy of the IUF, is that**
9 **what that's called?**

10 Q. IFU?

11 **A. IFU.**

12 Q. Mm-hmm. The same one that he went over
13 with you today?

14 **A. Mm-hmm (affirmative).**

15 Q. Okay.

16 **A. And she gave me a little bit of history**
17 **as to where this case was, and that this was one**
18 **case among many that was going to be eventually a**
19 **class action suit.**

20 Q. Well, that's -- the devil is in the
21 details?

22 **A. Right.**

23 Q. What history did she give you?

24 **A. History as to?**

25 Q. What did she tell you about this

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1 litigation?

2 A. She mentioned that it had several cases,
3 you know. I am sure there is many law firms that
4 has many cases, but they had many cases and that
5 they had hoped to present this to a federal judge in
6 West Virginia --

7 Q. Mm-hmm (affirmative).

8 A. -- sometime in July.

9 Q. Mm-hmm (affirmative).

10 A. And I guess she mentioned that this, they
11 consider to be -- this particular case to be a
12 middle of the road case, no extreme where they have
13 to go back 20 times for surgery, yet it was more
14 than just your simple vaginal erosion. So they felt
15 that this would maybe be a good test case for the
16 judge to look at.

17 Q. All right. How long did you meet with
18 her?

19 A. Approximately an hour.

20 Q. All right. And did -- other than the
21 IFU, did she go over any other documents with you?

22 A. I don't recall any other documents.

23 Q. Okay. Did she go over -- did you all go
24 over your medical record or chart with her?

25 A. We went over the medical records briefly.

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1 **Then I think we mentioned Dr. Nunnemann's op report**
2 **and his path report. I don't recall if she asked me**
3 **why I referred this patient to Dr. Nunnemann. But**
4 **you heard today why I did. That's about the extent**
5 **of that meeting.**

6 Q. All right. You said you briefly went
7 over the record. Out of this hour, how much time
8 did you spend actually on Mrs. Crews' medical
9 records?

10 **A. 20 to 30 minutes.**

11 Q. Okay. And the rest of the time was
12 talking about the litigation and the history and
13 whatnot?

14 **A. Catching me up to date on what this part**
15 **of the case was positioned and things.**

16 Q. Did you get the impression from her, or
17 did she tell you that the firm that they were --
18 that was representing Mrs. Crews had many other mesh
19 cases?

20 **A. She mentioned that.**

21 Q. Against many other mesh manufacturers?

22 **A. She mentioned the Ethicon. Obviously, I**
23 **didn't know about the AMS, but I think Bard was**
24 **mentioned.**

25 Q. Okay. Then when did you first meet with

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1 Mr. Blasingame?

2 A. I'll say about two weeks ago.

3 Q. How long did you meet with him?

4 A. Seems like it was longer, two hours
5 maybe.

6 Q. Was anybody else with his paralegal when
7 you met with her, or was it just the two of you?

8 A. It was just her. And then she was
9 present during Mr. Blasingale's [sic] first meeting.

10 Q. So in this longer meeting, what did y'all
11 do, what did y'all talk about?

12 A. Again, I think we talked a little bit
13 more about her medical records. We talked -- again,
14 there was two IFUs, 2008, 2011. He showed me those,
15 had me sign a confidentiality statement so they
16 could discuss those things that we brought up today.
17 Talked a little bit about flying as he was going
18 back home, he flew home.

19 Q. Okay. Anything else?

20 A. That's about the extent of what I
21 remember.

22 Q. Okay. Well, in this two-hour period how
23 much time did you spend talking about Mrs. Crews'
24 actual medical records?

25 A. Maybe 30 minutes.

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1 Q. Okay. So most of the time was really
2 these other documents --

3 A. Right.

4 Q. -- that you were talking about?

5 A. Mm-hmm, yeah.

6 Q. Did he show you all of the documents that
7 you saw here today?

8 A. I think he did. One document, the one
9 you couldn't find that was embedded, I don't
10 remember talking about that one.

11 Q. But there were a whole lot other more
12 documents that he showed you that you didn't go over
13 today; is that right?

14 A. There may have been a few that we didn't
15 go over; again, it's hard to recall all that.

16 Q. Did he put -- he made -- and we're going
17 to go over these today. There are a lot of
18 documents that have been produced, as you would
19 imagine, in litigation like this?

20 A. Mm-hmm (affirmative).

21 Q. Did he ask you to take these documents
22 home and read them so you could get a little context
23 or what?

24 A. Yeah. I think that they provided me with
25 the hospital records; of course, I had my own office

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1 **records.**

2 Q. Sure.

3 A. But I had the hospital records and the
4 records of Mayo. So they provided me those, asked
5 me to read those.

6 Q. What about these company documents that
7 he went over with you?

8 A. They didn't hand me any of those --

9 Q. Okay.

10 A. -- so they were just discussed. And he
11 may have shown them to me, but I didn't take
12 anything home.

13 Q. But in these types of e-mails and in
14 these meeting notes or minutes or whatever they
15 were, and we'll talk about them in a minute --

16 A. Mm-hmm (affirmative).

17 Q. -- did he show you any documents that
18 surrounded those that may have put those documents
19 into context?

20 A. Don't recall that.

21 Q. Okay.

22 A. Just the highlighted areas that he had.

23 Q. All right. Did he provide you with
24 copies of anything else?

25 A. No, I believe that's it.

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1 Q. Okay. And when was the next time that
2 you met with Mr. Blasingame this morning?

3 A. This morning.

4 Q. And what time did y'all meet this
5 morning?

6 A. We started meeting a little bit after
7 9:00, I believe --

8 Q. Okay.

9 A. -- a few minutes after 9:00.

10 Q. Okay.

11 A. We finished up about 10:30 or something
12 like that.

13 Q. And your attorney was present?

14 A. She was.

15 Q. Mr. Blasingame was present?

16 A. Can I refer the rest of the questions to
17 her?

18 Q. No, absolutely not.

19 I was not present; correct?

20 A. That's correct.

21 Q. All right. What did you talk about this
22 morning?

23 A. Again, I think he just refreshed my
24 memory on the IFUs. The -- I think he may have gone
25 over the -- some of the things he went over this --

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1 **you know, during his --**

2 Q. You're pretty sure he did, didn't you?

3 **A. -- deposition. Sorry?**

4 Q. Didn't you go over all these things that
5 you --

6 **A. Don't know that he went over all of them,**
7 **went over a few of them.**

8 Q. Did he tell you what kind of questions he
9 was going to be asking you?

10 **A. Yes. I guess in reference to that, he**
11 **asked me how I would answer that just to, I guess,**
12 **anticipate what my answer would be.**

13 Q. Did he provide you with a hypothetical,
14 for example, and say "how would you answer this one
15 if I give this hypothetical?"

16 **A. He did ask me a few hypotheticals. I**
17 **don't know that I can remember the contents of the**
18 **hypotheticals.**

19 Q. All right. Was there anything that you
20 can remember that you said, "no, I can't testify to
21 that"?

22 **A. Don't recall anything along that line.**
23 **(Defendant's Exhibit #1 marked)**

24 BY MS. DEMING:

25 Q. Doctor, we served a subpoena on you. I

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1 provided you an IFU; is that right?

2 **A. Yes.**

3 Q. And that was marked, I believe, as
4 Exhibit 7 this morning or earlier today.

5 **A. Okay.**

6 Q. Do you remember that testimony?

7 **A. I do.**

8 Q. Do you remember specifically ever having
9 read an IFU for the Prolift device?

10 **A. Can't say I remember specifically.**

11 Q. Okay.

12 **A. I may or may not have read one, so...**

13 Q. In your previous testimony did you say
14 that you typically didn't read instructions that
15 came from the manufacturer?

16 **A. You know, I guess in some things like,**
17 **you know, IUDs went off the market for a while and**
18 **then they came back on the market, you know, I**
19 **typically read those to refamiliarize. After you've**
20 **done several of them, then you don't really need to**
21 **go back and refer to them again.**

22 Q. And before you ever did a Prolift
23 procedure, you'd already done some Apogee and
24 Perigee procedures; right?

25 **A. I had assisted on a lot of those with**

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1 **Dr. Dohn and Dr. Johnston.**

2 Q. So would it, in fact, be the case then
3 that you didn't typically read IFUs like this
4 Prolift IFU?

5 A. Well, like I say, I honestly can't
6 remember if I did or didn't.

7 Q. When you gave that testimony before, was
8 it truthful?

9 A. What testimony did I give? That I
10 typically didn't --

11 Q. Do you remember giving any testimony
12 about whether you typically reviewed IFUs or not
13 before, or instructions from manufacturers?

14 MS. HOWANITZ: Do you want to show him
15 what you're referring to?

16 MS. DEMING: I can, and we can do it
17 later, so I don't --

18 BY MS. DEMING:

19 Q. But do you remember that testimony?

20 A. No. And like I say, I may not have
21 read -- may or may not have read that. But I
22 don't -- I know that I have read things for like
23 IUDs.

24 Q. For Apogees?

25 A. Yeah, for IUDs and those type of things.

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1 Q. Did you read the IFUs for the Apogee?

2 A. I don't recall --

3 Q. Okay.

4 A. -- to be honest.

5 Q. Okay. Going back to then your treatment
6 of Mrs. Crews when you did the TVT procedure, given
7 that you can't recall what IFUs you may have
8 reviewed or not reviewed, would it be a fair
9 inference that you certainly didn't rely on IFUs for
10 manufacturers to teach you how to use mesh products
11 and to do mesh procedures?

12 A. You're asking me if I relied on those, or
13 to --

14 Q. To treat your patients?

15 A. To treat the patient, no.

16 Q. Okay. When you did this TVT procedure
17 she came in for postop visit just like the one
18 postop for the Prolift procedure; right?

19 A. Mm-hmm (affirmative).

20 Q. Let me ask you to look at -- well, before
21 we do that, at Page 71 of your -- of the record
22 that -- your record, your chart, there is what's
23 called a Bladder Health Questionnaire at Pages 71.

24 A. Mm-hmm (affirmative).

25 Q. And then 73, I think, picks up with the

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1

A. I can't say that I have, no.

2

Q. Did Mr. Blasingame show you any of the

3

studies that are now three years and five years out

4

comparing the Prolift to other types of products?

5

A. He mentioned this morning that there's

6

been some new evidence that says that the mesh is

7

not any better than the conventional traditional

8

method as far as recurrence rate.

9

Q. Did he tell you that there is literature

10

out there showing that it's not any worse?

11

A. I am sure that's true.

12

Q. Okay. Did you read any of the studies

13

that he told you about?

14

A. He didn't reference as to which studies

15

he was speaking of, so...

16

Q. So you know any time you read a study,

17

it's got its good points, it's got its bad points;

18

right?

19

A. Kind of like the Bendectin case?

20

Q. Kind of like that. And at the end of

21

those published articles, there is usually a

22

reference to what the limitations of the study are,

23

what really you can infer or conclude from these

24

studies; right?

25

A. And the weaknesses of the strengths of

1 **the studies; right.**

2 Q. Did he point any of that out to you when
3 he was talking about it?

4 **A. Not that I recall, no.**

5 Q. He went over a whole bunch of risks of
6 mesh products. Did he show you any evidence that
7 suggested the risks that we talked about most of the
8 morning were confined to the Prolift as opposed to
9 being common to all mesh products?

10 **A. I don't think it was specifically for any**
11 **particular product as being true of all mesh**
12 **products.**

13 Q. Let me ask you to look at these Exhibits
14 that Mr. -- just have those before you, if you will.

15 **A. Okay. Are we finished with Exhibit 5?**
16 **Can I hand it back or hold on to it?**

17 Q. Yes, I think so. I think so.

18 **A. It would give me a little bit more space**
19 **down here.**

20 Q. Okay. Look at Exhibit 1.

21 **A. Okay.**

22 Q. All right. And this is a multipage
23 document that purports to be notes that somebody
24 took at a meeting of experts; is that right?

25 **A. That's what it appears to be, yes.**

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1 Q. Okay. And you'd never seen this document
2 before Mr. Blasingame showed it to you, did you?

3 A. That's correct.

4 Q. All right. And you don't know any of
5 these people, do you?

6 A. I thought I knew the Dennis Miller, but I
7 think it's another person I'm thinking of. No, I
8 don't know any of these people.

9 Q. Well, we all know Dennis Miller is a
10 great comedian.

11 A. Right.

12 MR. BLASINGAME: He's also a
13 urogynecologist out there in Minnesota, I think.

14 BY MS. DEMING:

15 Q. You don't know a urogynecologist from
16 Minnesota, do you?

17 A. No.

18 MR. BLASINGAME: Have we got that?
19 Excuse me. Have you got your copy of that Exhibit?

20 MS. DEMING: I do have my copy.

21 MR. BLASINGAME: Okay. I was just -- I
22 don't put my hand -- may I see that? Yes.

23 A. Yeah, this is Exhibit 1. That might be
24 your copy.

25 MR. BLASINGAME: Okay. Yeah, it may be.

1 MS. DEMING: I'm sorry. These were your
2 documents so I thought you had retained copies. I
3 mean documents that you had showed him during your
4 examination of him.

5 BY MS. DEMING:

6 Q. Doctor, do you know the context in which
7 that meeting was held?

8 A. No, except for what's written here, you
9 know, it just says Expert Meeting, Meshes for Pelvic
10 Floor Repair.

11 Q. Okay. Did you -- do you agree it's a
12 good thing for companies to meet with key opinion
13 leaders and thought leaders and experts in the
14 field?

15 A. I think it's an excellent thing to look
16 at ways of improving their products.

17 Q. And that's a very good thing to always be
18 striving to make the product better; correct?

19 A. That's correct.

20 Q. And that's the way medicine works, isn't
21 it, Doctor?

22 A. That's correct.

23 Q. And just because more is learned about a
24 product that allows a better product to be developed
25 doesn't mean that first product was defective;

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1 right?

2 **A. That's correct.**

3 Q. Did you read this whole document that he
4 took selections -- took selected portions of --

5 **A. No.**

6 Q. -- from Exhibit 1?

7 **A. Just the areas that he had gone over in**
8 **the previous deposition.**

9 Q. All right, Doctor. When you go to
10 meetings and you take notes, do those notes always
11 have everything that was covered in those meetings?

12 **A. No.**

13 Q. Okay. Do you have any idea who was even
14 taking the notes that are reflected here?

15 **A. Don't believe that's reflected.**

16 Q. Okay. You certainly had never seen it
17 before Mr. Blasingame showed it to you; right?

18 **A. No.**

19 Q. Did he show you any other documents that
20 put that document into context?

21 **A. I can't really say that he did. I know**
22 **that this is confidential information because I**
23 **signed a confidentiality statement.**

24 Q. All right. Look at Exhibit 2. What was
25 Exhibit 2? Do we -- is that one there? It's the

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1 next one. It is.

2 MS. HOWANITZ: PowerPoint presentation.

3 MS. DEMING: Oh, it's the PowerPoint.

4 Okay.

5 BY MS. DEMING:

6 Q. Mr. Blasingame only asked you two
7 questions -- or strike that. He asked several
8 questions. But he referred to page --

9 MR. BLASINGAME: May I see that one just
10 a second?

11 THE WITNESS: Sure.

12 MS. DEMING: That's the real thick one.

13 MR. BLASINGAME: Oh, okay. That's the
14 only copy I had, I think.

15 BY MS. DEMING:

16 Q. Well, this is -- you referred to -- or
17 strike that.

18 Mr. Blasingame referred to Page 20 of
19 that document, and Page 107 of that document; right?
20 You don't need to interpret it. I'm just asking
21 trying to refresh your memory. There were only two
22 pages out of there that he referred to.

23 **A. This is not a trick question?**

24 Q. Not a trick question. Have you ever seen
25 that document before?

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1 **A. No, I have never seen it before.**

2 Q. It's 140 pages; right?

3 **A. Mm-hmm (affirmative).**

4 Q. And if you look at the last number, it's
5 got 140 pages in it. Did you read every single page
6 of that?

7 **A. No.**

8 Q. Of course not.

9 MR. BLASINGAME: What was that comment
10 you made?

11 MS. DEMING: I'll withdraw that comment.
12 I said: "Of course not."

13 BY MS. DEMING:

14 Q. Do you know the context in which this
15 PowerPoint was even put together?

16 **A. Not entirely, no.**

17 Q. Have you ever used a PowerPoint in making
18 any presentations?

19 **A. I have.**

20 Q. And how do -- strike that.

21 Do your PowerPoint references just kind
22 of summarize a point that you might make, but it
23 certainly doesn't include everything you say about
24 that point, does it?

25 **A. Usually that's the case, yes.**

1 Q. So it's more of a prompt to talk about
2 other things; right?

3 A. **Keep you on task, right.**

4 Q. Do you know what was discussed in the
5 context of these individual PowerPoint slides?

6 A. **I don't. I don't.**

7 Q. We talked about this a little bit earlier
8 that doctors have different preferences for things;
9 right? Do you remember that testimony?

10 A. **That's correct. That's correct, mm-hmm.**

11 Q. And some feel like, well, this product
12 doesn't meet this need I have. Do you agree that
13 happens?

14 A. **Yes; different doctors have different**
15 **opinions.**

16 Q. Just like you tended to use Apogee and
17 Perigee because you were experienced and familiar
18 with that, that was your preference; right?

19 A. **That's correct.**

20 Q. Do you think it's a bad thing for a
21 company like Ethicon to try to develop a product
22 that meets some of these unmet needs?

23 A. **I think that's a thing they should be**
24 **striving for, yes.**

25 Q. And just because a salesperson giving a

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1 PowerPoint presentation talks about unmet needs, you
2 don't think that's synonymous with defects in the
3 product, do you?

4 MR. BLASINGAME: Object to the form of
5 question.

6 A. No, I think a company that's striving for
7 improvements should look at their weaknesses and try
8 to improve upon them.

9 BY MS. DEMING:

10 Q. All right. With respect to adverse
11 events, I asked you if you had reported this event
12 to the FDA, and Mr. Blasingame asked you a lot of
13 questions about what you would have done and what
14 you wouldn't have done. You certainly didn't --

15 MR. BLASINGAME: Object to the form of
16 that question.

17 MS. DEMING: Okay.

18 BY MS. DEMING:

19 Q. You certainly didn't expect --

20 MR. BLASINGAME: Excuse me. I object to
21 the comment. It wasn't a question.

22 MS. DEMING: Oh, well, whatever.

23 MR. BLASINGAME: Whatever.

24 BY MS. DEMING:

25 Q. Doctor, did you expect -- well, strike

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1 that.

2 You understand that adverse events can be
3 reported for any number of things to a drug company;
4 right?

5 **A. That's correct.**

6 Q. And they don't necessarily mean that
7 product caused that problem, it's just a report that
8 somebody gives to the company about some malady they
9 have. Is that your understanding?

10 **A. That's my understanding.**

11 Q. And do you think it's a good thing for
12 companies to evaluate reports and see if there is
13 any merit and assess the validity of reports of
14 adverse events before they start disseminating
15 information about that?

16 **A. Yes. I think that, you know, they want
17 to verify the accuracy of those reports before
18 disseminating information.**

19 Q. And that can take some time, you agree?

20 **A. It certainly can take some time.**

21 Q. Misinformation would be worse than no
22 information at all, don't you think, Doctor?

23 **A. In most cases I would have to say that's
24 true.**

25 Q. So when Mr. Blasingame asked you

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1 questions about whether you would want to know
2 everything that a drug company knows about the
3 product, you don't want to know everything, do you,
4 Doctor?

5 **A. It's hard to fairly answer that. I would**
6 **like to know known potential risks, you know, before**
7 **so I can make an informed decision for the patient.**

8 Q. I don't disagree with that, Doctor.

9 MR. BLASINGAME: Excuse me. I object to
10 your comment.

11 MS. DEMING: I will withdraw the comment.
12 BY MS. DEMING:

13 Q. Doctor, you expect the company, though,
14 to evaluate those reports so that they can provide
15 you accurate and up to date information; correct?

16 **A. That's correct.**

17 Q. Exhibit 3, Doctor, if you'll look at
18 that.

19 **A. Okay.**

20 Q. Just as we discussed with Exhibit 1, you
21 understand this to be notes again from somebody that
22 attended a meeting in 2006; right?

23 **A. That's correct.**

24 Q. Do you know anything about the context of
25 this meeting?

1 **A. No, except they are talking about meshes**
2 **for pelvic floor repair.**

3 Q. Okay. Well, and that's based on what you
4 read there; right?

5 **A. Exactly.**

6 Q. And what Mr. Blasingame told you about
7 that document; right?

8 **A. He has referred to this document, yes.**

9 Q. Okay. Did you read the whole thing?

10 **A. I have not read the whole thing.**

11 Q. Did he go over this with you before your
12 testimony began today?

13 **A. He mentioned elements of this document**
14 **that he questioned whether or not I was aware of**
15 **them --**

16 Q. Okay.

17 **A. -- the information therein.**

18 Q. And, again, you don't know what was
19 discussed that may not have appeared in this
20 person's notes; right?

21 **A. I don't know -- can you rephrase?**

22 Q. You don't know if there was other stuff
23 discussed --

24 **A. No, no.**

25 Q. -- that just didn't appear in the

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1 notes --

2 **A. Right.**

3 Q. -- isn't that right?

4 **A. No, I'm not privy to all the information**
5 **that was at that meeting.**

6 Q. Do you know anything or did
7 Mr. Blasingame show you any documents to put this
8 one into context?

9 **A. No, no other documentation.**

10 Q. Once again, you agree it's good for
11 companies to meet with thought leaders and experts?

12 **A. I would expect them to, yes.**

13 Q. If you'll look at Exhibit 4, Doctor.

14 **A. Okay.**

15 Q. Okay. This was an e-mail that
16 Mr. Blasingame talked to you about earlier today?

17 **A. That's correct.**

18 Q. Strike that. I apologize. I was getting
19 in a hurry.

20 Do you know Anne Doherty?

21 **A. I don't.**

22 Q. Have you ever talked to Anne Doherty?

23 **A. I don't believe I have.**

24 Q. Do you know Kim Hunsicker?

25 **A. I don't believe I do.**

1 Q. Had you ever seen this document before
2 Mr. Blasingame showed it to you?

3 A. No, I had not.

4 Q. Did he show you any of the documents or
5 the context of these e-mails, any other documents to
6 put it into context?

7 A. Not that I recall.

8 Q. Did you read the whole string of e-mails
9 that go along with this?

10 A. I have not.

11 Q. Wouldn't you want to know the context of
12 these documents and the context of these selective
13 quotes that Mr. Blasingame told you before you make
14 a decision as to whether these would even have had
15 any effect on what you told Mrs. Crews?

16 A. Can you -- can you rephrase that
17 question?

18 Q. Well, Doctor, I have gone through these
19 documents with you. You don't know what they are?

20 A. No.

21 Q. You'd never seen them before?

22 A. That's correct.

23 Q. You haven't seen documents to put them
24 into context?

25 A. That's correct.

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1 Q. You haven't even read the documents.
2 You've just listened to Mr. Blasingame's rendition
3 and selective portions of those documents; right?

4 A. That's correct.

5 Q. Just like you talked about in what you
6 would do and what you would rely on to treat your
7 patients --

8 A. Mm-hmm (affirmative).

9 Q. -- you would want to know the context of
10 the statements Mr. Blasingame read to you from these
11 documents before deciding, or before telling this
12 jury that we're going to be before, whether these
13 documents or this information would have made any
14 difference to you; right?

15 A. That's correct.

16 Q. Doctor, when you met with any of the
17 folks from Mr. Blasingame's office, did they say to
18 you at the outset something to the effect of "now,
19 we don't criticize your treatment, we don't have any
20 problem with you whatsoever." Was that statement
21 made to you or implied to you?

22 A. Maybe implied. They did tell me that
23 they are representing Mrs. Crews, not me. I think
24 just the nature of my records and the length of time
25 before she had a problem, they kind of reassured me

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2 You've just listened to Mr. Blasingame's rendition
3 and selective portions of those documents; right?

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6 would do and what you would rely on to treat your
7 patients --

8 A. Mm-hmm (affirmative).

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10 the statements Mr. Blasingame read to you from these
11 documents before deciding, or before telling this
12 jury that we're going to be before, whether these
13 documents or this information would have made any
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17 folks from Mr. Blasingame's office, did they say to
18 you at the outset something to the effect of "now,
19 we don't criticize your treatment, we don't have any
20 problem with you whatsoever." Was that statement
21 made to you or implied to you?

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23 they are representing Mrs. Crews, not me. I think
24 just the nature of my records and the length of time
25 before she had a problem, they kind of reassured me

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1 **that they don't feel like anything was done**
2 **inappropriately by me.**

3 Q. Okay. Did any remark -- strike that.
4 Was any remark made or implied by --
5 strike that.

6 Was there any remark that was made, or
7 did you draw an inference from the remarks that were
8 made that somehow Ethicon was going to point the
9 finger at you, or throw you under the bus, or
10 something to that effect?

11 A. I do recall I guess it was Ann Parker,
12 she said in terms of law -- she made it easy for me.
13 She says we talk about three Ps: Patient, product
14 and physician. And she says we represent -- not
15 blaming the product, obviously, so you're either
16 going to point the finger at the physician or the
17 patient.

18 Q. Okay. And that was in this first meeting
19 you had with her?

20 A. That was in this first meeting.

21 Q. Why do you think she told you that,
22 Doctor?

23 A. I think it was just to kind of give me
24 where you might be coming from.

25 Q. Okay. Maybe poison the well?